**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| UNITED STATES ex rel. BERNARD LISITZA, et al., | ) | |
| Plaintiffs, | ) | No. 06 C 06131 |
| v. | ) | Judge John J. Tharp, Jr. |
| PAR PHARMACEUTICAL COMPANIES, INC., | ) | |
| Defendant. | ) | |

**MEMORANDUM OPINION AND ORDER**

In this *qui tam* action brought primarily under the federal False Claims Act and parallel state statutes, the plaintiffs—the United States, the State of Michigan, and the State of Indiana—allege that defendant Par Pharmaceutical Companies, Inc., caused national pharmacy chains to submit false claims for reimbursement from Medicaid by inducing them to fill prescriptions not with the generic drugs originally prescribed but with more expensive forms and dosages of those drugs manufactured by Par. The plaintiffs maintain that the pharmacies' reimbursement claims were "inherently" false because the pharmacies "overcharged" the government, but that argument reads the requirement of a false or misleading statement out of the False Claims Act. The reimbursement claims were not "inherently" nor expressly false simply because the government paid more for Par's drugs than it would have paid for the form or dosage that was originally prescribed.

The plaintiffs also maintain that the claims were false because they omitted information that the drug for which reimbursement was sought was not the originally prescribed drug but an alternate form or dosage strength selected to circumvent the reimbursement cap that applied to

the originally prescribed drug, without regard for regulations requiring physician authorization and the dispensing of only medically necessary and economical treatments. The claims therefore implicate the Supreme Court's recent decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), which addressed the scope of liability under the False Claims Act for "implied false certification," that is, the submission of claims that omit material information about regulatory non-compliance. Par maintains, and the Court agrees, that under the standard established in *Escobar*, the reimbursement claims it submitted were not false or misleading.

Furthermore, Par's motion argues that the plaintiffs lack evidence of even one claim for reimbursement for a drug that was switched in a manner that arguably violated the law because there was no physician approval, no demonstration of "medical necessity," and no proof that the drug dispensed was the most "economical" choice. The plaintiffs did not put proof of any such claim in the record; they refer to their expert witnesses' identification of statistical trends instead, and argue that they have no burden until trial to show evidence of the false claims. But that is not how summary judgment works. The plaintiffs have not presented evidence sufficient to support a finding that any particular claim the pharmacies filed was false, even according to their own theory. Accordingly, Par's summary judgment motions are granted.

## I. BACKGROUND

This is the fourth of a related set of four *qui tam* FCA suits, the first dating from September 2001, which the relator Bernard Lisitza filed against the pharmacies Omnicare, Walgreens, and CVS, respectively, and finally against Par and three other drug makers that are no longer defendants. All allege an unlawful prescription-switching scheme (*i.e.*, the unauthorized substitution of more expensive pills) that resulted in overcharging the Medicaid

program and, therefore, violating the FCA. In this case, the United States and the states of Michigan and Indiana intervened and filed separate complaints. Many other states permitted the relator to litigate their claims for them.[1] In the current motions Par seeks summary judgment on the merits against the United States, Michigan, and Indiana, arguing that it is entitled to judgment as a matter of law because the plaintiffs cannot establish the falsity of the claims on which the lawsuit is based.

### A. The Complaints

The operative pleading of the United States is the Corrected Second Amended Complaint of July 9, 2013, which names only Par as a defendant. *See* Corrected Second Amended Complaint ("CSAC"), ECF No. 231. Michigan and Indiana filed their own complaints, *see* Mich. Compl., ECF No. 69; Ind. Am. Compl., ECF No. 148. Although the complaints are separate, and Par moved against each plaintiff separately, the complaints are substantially similar and the United States, Michigan, and Indiana filed a joint opposition brief and joint statements of fact. Accordingly, except where necessary to distinguish between these governmental parties, this opinion will simply refer to all three of these governmental parties as "the plaintiffs."

In general, the plaintiffs allege that Par orchestrated an illegal prescription-switching scheme by developing or acquiring the rights to manufacture and/or distribute widely available generic drugs, but in different dosage strengths or forms than those commonly offered by competitors, and then marketing its drugs to pharmacies based on their ability to obtain higher Medicaid reimbursements for Par's products, which were not subject to standard reimbursement caps because they were so unusual. To effect the scheme, the pharmacies programmed their

[1] In a separate opinion today, the Court dismissed the complaint of the relator pursuant to the FCA's public disclosure bar. Accordingly, the claims of the non-intervening states have also been dismissed and are not addressed in this opinion.

automated systems to automatically switch drugs to Par's atypical versions of commonly prescribed medications. Specifically, this case pertains to the following so-called "subject drugs": 10- and 20-mg tablets of fluoxetine (generic Prozac, an anti-depressant), 150- and 300-mg capsules of ranitidine (generic Zantac, an antacid), and 7.5-mg tablets of buspirone (generic Buspar, an anti-anxiety medicine). Par's drugs were alternatives to the fluoxetine capsules in the same strengths, ranitidine tablets in the same strengths, and buspirone tablets in a 15-mg strength—the dosage most commonly prescribed. This case relates only to the dispensing of the subject drugs by two pharmacies, Omnicare and Walgreens. More precisely, the complaint alleges that Par induced Omnicare to offer its fluoxetine and buspirone products, but not ranitidine, the third subject drug. Walgreens is alleged to have dispensed all three subject drugs.

The plaintiffs assert that the subject drugs were dispensed without physician approval, were not "medically necessary," and were not economical within the meaning of governing state and federal Medicaid regulations, and further that Par and the pharmacies acted solely based on a profit motive, all in violation of the False Claims Act because their actions violated the regulations and consequently inflated the costs to Medicaid. The plaintiffs also allege a conspiracy between Par and the pharmacies, as well as common-law fraud; finally, Michigan and Indiana separately allege state common-law torts of unjust enrichment (both), and theft and offense-against-property (Indiana only).

**B. Par's Motions**

In seeking summary judgment on the merits, Par argues that the plaintiffs cannot meet their burden of establishing that Par caused the submission of claims that were false within the meaning of the FCA or the parallel state statutes. Par further argues that the other claims

necessarily fail as well, based on the absence of falsity. This opinion jointly addresses Par's three motions.

Since the close of briefing, the parties have filed, with leave of court, supplementary briefs addressing the impact of the Supreme Court's decision in *Universal Health Services, Inc. v. United States and Massachusetts ex rel. Escobar and Correa* ("*Escobar*"), 136 S. Ct. 1989 (June 16, 2016). *See* Pls. Suppl. Brief, ECF No. 398; Par Suppl. Br., ECF No. 399. That case pertains to the so-called "implied false certification" theory that, according to Par anyway, is the theory underlying the plaintiffs' FCA claims.

In reviewing the motions for summary judgment, the Court must view the facts and draw reasonable inferences in favor of the non-moving parties, to the extent they are supported by the record. *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 823 (7th Cir. 2011). Under Local Rule 56.1(a)(3) & (b)(3), the parties must set forth, and respond to, proposed undisputed facts and provide support with admissible evidence. *See also* Fed. R. Civ. P. 56(c) & (e). They have done so here, albeit with a great deal of improper argument folded in. The bulk of the factual disputes presented by the parties are not material to the resolution of these motions, which simply argue that the plaintiffs cannot prove falsity as a matter of law. The immaterial facts are omitted.

## II. FACTS

The Medicaid program, one type of government-sponsored insurance, is a Third Party Payor ("TPP") that reimburses pharmacies for the cost of filling prescriptions dispensed to the program participants. Under the Medicaid system, retail and institutional pharmacies (such as Omnicare, which operates primarily in nursing homes) provide prescription medications to customers and then file claims for reimbursement from the relevant state or federal agency that

administers Medicaid and sets the reimbursement rate. State and federal Medicaid agencies establish their reimbursement rates for prescription drugs, which they cap in the form of a Federal Upper Limit ("FUL") or, under state law, a Maximum Allowable Cost, or "MAC." The Court will adopt the parties' convention of referring to "MACs" as inclusive of all reimbursement caps. These MACs are typically set with reference to market conditions and the actual costs of the drugs. With certain drugs, however, the Average Wholesale Price determines the reimbursement rate; this generally results in a much higher reimbursement rate because AWPs are benchmarks prices set by manufacturers with little or no relation to the drug's cost. The AWP is used when there are too few active sellers of a given drug to allow the TPPs to set reimbursement rates according to their market-based formulas. At various times, Par's drugs at issue in this case commanded reimbursement rates based upon the Average Wholesale Price method, in contrast to the same drugs in the market with different (and, at least initially, more common) dosages and forms, which were capped by MACs.

When a new generic drug comes to market, the Food and Drug Administration grants a 180-day exclusive marketing period to the manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iv). MACs are not set until that period expires and other sellers enter (or do not enter) the market. No MAC is set unless other sellers materialize. A "new" drug under FDA regulations is not related solely to its active ingredient; each separate dosage strength and format needs its own approval and is separately priced for reimbursement. Thus, for example, 10-mg fluoxetine tablets are not regarded by the FDA as the same drug as 10-mg fluoxetine capsules, and two 7.5-mg buspirone tablets are not the same as one 15-mg tablet.

The two pharmacies at issue in this case against Par, Walgreens and Omnicare, entered into Medicaid Provider Agreements with the federal government and the states in which they

operated. These agreements contained certain conditions of participation in the Medicaid program, most of which contain the following terms quoted here from the state of Florida's 2003 enrollment agreements,[2] with immaterial differences:

> The Provider agrees to participate in [Medicaid] under the following terms and conditions:
>
> * * *
>
> (2) Quality of Service. The provider agrees that services or goods billed to the Medicaid program must be medically necessary, of a quality comparable to those furnished by the provider's peers, and within the parameters permitted by the provider's license or certification.
>
> (3) Compliance. The provider agrees to comply with local, state, and federal laws, as well as rules, regulations, and statements of policy applicable to the Medicaid program, including the Medicaid Provider, including the Medicaid Provider Handbooks issued by the [responsible Medicaid agency].

See Pl. Resp. SOF §¶ 18, ECF No. 370. As relevant to part (3), every Medicaid jurisdiction in this case has some requirement that treatments be medically necessary and the most cost-efficient or economical (various terms are used) available. The conditions of enrollment are enforceable with penalties including suspension from the Medicaid program. The plaintiffs' brief contains an addendum setting forth the applicable laws of every plaintiff state. See Addendum of Laws, ECF No. 369-1.

The pharmacies submitted reimbursement claims to Medicaid after filling prescriptions with Par drugs, as they would do with any other drugs they dispensed. A standard form required

[2] The parties' citation to Florida rules is odd, as that State's claims are not at issue in this motion, whereas Par's motion directly attacks the complaints of the United States, Michigan and Indiana. The Court has ferreted out one exhibit featuring a 2002 executed Michigan provider agreement and a Billing Agent Authorization. *See* Exhibit 50 to Corrected Second Amended Complaint, ECF No. 232-3. But only the faces of these documents are included, and not the reverse sides, referenced on the front sides, that contain the relevant certification language. If the parties agree that the certifications are the same or similar, it is a mystery why Florida forms were chosen as the examples rather than one of the plaintiffs'.

the pharmacy to set forth: a provider number, a total amount billed, the name of patient, the National Drug Code for the drug dispensed (not "prescribed"), the prescription number, and the date filled. Sample Claim Form, ECF 232-3. The forms typically were submitted electronically. All claim forms require a provider certification that "***the foregoing information is true, accurate, and complete***." Pl. Fact Resp ¶ 51, ECF No. 370. They further require acknowledgement that "***payment and satisfaction of the claim will be from Federal and State funds, and that any falsification of claims, statements or documents, or concealment of material fact may be presented under applicable Federal or State laws***." *Id*. There are few claim forms made part of the summary-judgment record, but Par does not dispute that Walgreens and Omnicare sought reimbursement from Medicaid for hundreds of thousands of prescriptions for the subject drugs during the relevant time period, nor that the claim forms contained the quoted language or its substantial equivalent.

The premise of the complaints is that Par convinced Walgreens and Omnicare to offer its products, rather than the standard forms and dosages then prevailing in the market, by emphasizing the greater profitability of selling Par's non-MAC-controlled products. The pitch was straightforward: sell Par's products; receive higher reimbursements; make more profit. Some exceptions existed—Par notes occasions when its drugs had reimbursement rates that were equivalent to or lower than the MAC set for the competition—and we will come back to these later. But there is no fundamental dispute that, over the course of the scheme, reimbursements for the subject drugs far exceeded what Medicaid would have paid if MAC-capped dosages and forms had been dispensed instead of the subject drugs.

Par marketed its subject drugs to Walgreens and Omnicare based at least in part on the absence of MACs on its products, and it was Par that approached the pharmacies to market its

atypical offerings (which is not to say who devised the prescription-switching scheme; that fact is disputed). Par was aware that FULs were not set for drugs without at least three active sellers, and that states had broader discretion over setting MACs. Par was generally aware of the reimbursement rates on ranitidine, fluoxetine, and buspirone, and it made assumptions or predictions about limits that might be established, or modified, in the future. Par prepared financial projections highlighting the potential profitability of switching from the more common forms and dosage strengths; these projections were, at least, used as talking points for the marketing executives and might have been physically shared with the pharmacies' purchasing executives. To suggest the legality of its proposal, Par also commissioned a "survey" of each state's Board of Pharmacy regarding policies relevant to dispensing generics (in this instance, fluoxetine); that survey as presented (or used in marketing presentations) to the pharmacies did not include the states' requirements that Medicaid services be medically necessary and provided in a cost-effective, economical manner. The survey was prepared by a pharmacist, not a lawyer.

To persuade the pharmacies of the long-term benefits of switching, Par used its industry knowledge to predict that it was unlikely that competition from other sellers would materialize in the future, after Par's exclusivity rights expired. Beyond the benefit of greater reimbursements, Par offered other financial incentives to the pharmacies to switch to its drugs and to purchase them in large quantities; these included rebates while the switching was ongoing. Later, Par offered price reductions on other products to offset the pharmacies' profit losses once the switching scheme ended in 2004 due to government investigations.

The pharmacies grasped the opportunity to increase their profits through higher Medicaid reimbursements and aggressively sold the switching plan internally, all the way down to the retail pharmacists dispensing the drugs. They adjusted their computer systems to automatically

suggest Par's versions of the subject drugs, and over time, the pharmacies typically dispensed Par's subject drugs although there is no evidence that the frequency with which physicians actually prescribed the atypical dosage strengths and forms Par distributed increased at all, let alone exponentially.

As an example of the implementation of the scheme, in April 2001, the predecessor agency to the Centers for Medicare and Medicaid Services (CMS) issued a bulletin announcing the imminent issuance of FULs for 150 mg and 300 mg ranitidine tablets. Capsules were not mentioned. By August, Par was aware that fewer than three firms would actively sell capsules and it assumed, therefore, that no FUL would be set for capsules; this was confirmed when CMS issued the FULs for the tablets only. Par prepared a chart entitled "Walgreens Ranitidine Analysis (tablets vs. gelcaps)" that it used as part of its marketing of the subject drugs to Walgreens. Par's model also suggested that, based on certain assumptions, the cost to Walgreens of acquiring Par's capsules could be higher than what it would pay for tablets (diminishing any price motive for the pharmacies if those assumptions held true). But Par also offered rebates and price reductions to customers who purchased the subject drugs in bulk to provide additional financial incentives for the pharmacies to switch.

Par approached Walgreens, including its Director of Pharmacy Marketing, Tom Lawlor, to pitch its ranitidine capsules, and in the process suggested that Walgreens could make more money dispensing Par's capsules because there was no MAC. The Par executives involved in marketing the ranitidine included Nick DiMaio, Julee Tredowicz, and Scott Tarriff. By July 2001, Walgreens had contracted with Par for purchases of ranitidine capsules and instituted a program in which its front-line pharmacists would dispense capsules instead of tablets (with physician approval, Par says). Internally, a Walgreens purchasing executive, Bill Groth,

explained that the switching was due to the MACs set for tablets and the potential to greatly increase profits with capsules. Groth also referred to a lower acquisition cost for Par's drugs. Lawlor sent an email instructing that store managers should explain to "staff" (*i.e.*, pharmacists) that "MAC pricing on tabs (and no MAC on caps) plus rebates has forced our hand." Walgreens programmed its computerized prescription-filling system to "suggest" capsules for any ranitidine prescription. Lawlor referred to this in a company-wide email as "automatically switching" the drugs. The system permitted pharmacists to override the suggestion, but neither party adduced evidence of the frequency with which they did so. Between July and October 2001, Walgreens earned up to $259,460 more in gross profit by dispensing Par's capsules instead of tablets, based upon the plaintiffs' models projecting the profits if Walgreens had, hypothetically, dispensed the tablets and received the FUL reimbursement rate (as opposed to any particular states' MACs). Over the period of 2000 to 2006, the government estimates "differential losses" to state and federal governments of $14,028,549, just from Walgreens' claims for reimbursement for Par's ranitidine capsules. In short, the profits were higher, as predicted by Par and hoped for by Walgreens. Par implemented its marketing scheme in much the same way with Omnicare and Walgreens as to the other subject drugs. It is not necessary to the disposition of these motions to set forth these transactions in the same level of detail.

After the Illinois Department of Health sent a formal warning to Walgreens on July 25, 2001, that dosage-form switching to non-equivalent[3] products required documented physician permission; Lawlor emailed all Walgreens pharmacies emphasizing this mandate. It is unclear whether the pharmacists had previously been instructed on the issue, although Lawlor testified

[3] Again, because of distinctions relating to effectiveness and safety, under state and federal law each dosage strength or form is treated as a separate drug, even if the active ingredient is identical.

that to his knowledge, proper procedures were followed. Whether because pharmacists were already obtaining permission or because they chose to ignore the warning, it did not abate the switching, which continued with the same frequency after the warning.

Over the course of the alleged scheme, due to fluctuations in the applicable MACs, there were some claims that Walgreens submitted for ranitidine capsules that were reimbursed at the same or a lower rate than the more-common alternates; the plaintiffs estimate this to have occurred about 10% of the time, and they do not seek to recover on such claims as part of this lawsuit. See Pl. Stmt. Add'l Facts ¶ 74, ECF No. 371. The same phenomenon occurred with the other subject drugs at times, and the plaintiffs also exclude those claims from the universe of allegedly inflated claims. *Id*. ¶ 75.

## DISCUSSION

Summary judgment "shall" be granted if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Yahnke v. Kane Cty., Illinois*, 823 F.3d 1066, 1070 (7th Cir. 2016). In opposing a summary judgment motion, it is the plaintiffs' burden to identify record evidence sufficient to support a jury verdict in their favor. *Yannacopoulos*, 652 F.3d at 823 (in opposing summary judgment, a plaintiff must present evidentiary material sufficient to allow him to carry his burden of proof); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 330 (9th Cir. 2017) ("To survive summary judgment, the relator must establish *evidence* on which a reasonable jury could find for the plaintiff."). The underlying substantive law governs whether a factual dispute is material; irrelevant factual disputes do not preclude summary judgment. *Carroll v. Lynch*, 698 F.3d 561, 564 (7th Cir. 2012) (citing *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986)).

A factual dispute is genuine when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

As relevant here, 31 U.S.C. § 3729(a) imposes liability on any entity that: (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement "material to a false or fraudulent claim; [or] (3) "conspires to commit a violation of" any part of § 3729(a).[4] There is no dispute here that the Medicaid reimbursement requests submitted by the pharmacies are "claims" within the definition of the FCA. 31 U.S.C. § 3729(b)(2)(A).

Par seeks judgment principally on the ground that the plaintiffs have not proved "the essential element of falsity." Par Reply 2, ECF No. 375. More specifically, Par seeks summary judgment on the basis that the plaintiffs cannot prove that Walgreens or Omnicare submitted any "false" claim for reimbursement based on their dispensing any of Par's drugs. *Id*. at 1. Par contends that the claims were not "false" under the FCA and that the plaintiffs failed to adduce evidence of any particular claims that were submitted about drugs proven to have been switched to a Par subject drug without physician approval, medical necessity, and/or cost-effectiveness. Since Par expressly disclaims any other bases for summary judgment, none will be considered here. To survive Par's summary judgment motion, then, the plaintiffs must be able to point to evidence from which a reasonable jury could conclude that the pharmacies made a false statement in order to obtain reimbursement from the government for dispensing the subject drugs. *United States ex rel. Sheet Metal Workers Int'l Ass'n, Local Union 20 v. Horning Investments, LLC*, 828 F.3d 587, 592 (7th Cir. 2016). *See also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) ("Federal rules "mandate the entry of summary judgment, after adequate time

[4] The citation is the FCA as amended in 2009, because § 3729(a)(1)(B) applies to cases pending on or after June 7, 2008. *See Yannacopoulos*, 652 F.3d at 822 n.2

for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.").

### A. The Reimbursement Requests Were Not "False Claims" Under the FCA

In arguing that the claims at issue in this case were not false as a matter of law, Par contends that the claim forms contained no false or misleading representations. Par also challenges the evidentiary basis for the plaintiffs' claims, arguing that there is no evidence that physician approval had not been obtained for the claims at issue,[5] nor that the switching violated the regulations pertaining to medical necessity and cost-effectiveness.

#### 1. Intervening change in the law governing the FCA

After Par's motions were filed and briefing was under way, the legal landscape changed significantly in this Circuit. The development pertains to two theories of falsity under the FCA: false certification and implied false certification—in essence, falsity resulting from express misrepresentations or from misrepresentation by omission.

When Par first moved for summary judgment, the Seventh Circuit had not accepted the implied-false-certification theory of FCA liability, and before the plaintiffs filed their joint

[5] The government sidesteps this argument by branding it irrelevant. In apparent acknowledgment that record evidence supports the conclusion that physician approval was requested in some cases, the government contends that any such requests were *pro forma* and any approvals were unknowing—and, further, that "physicians cannot bilk Medicaid any more than pharmacies can." Mem. 29, ECF No. 369. This appears to be a concession that the government does not have a claim-by-claim accounting of which claims are for drugs that were switched with, or without, physician approval. Perhaps it is because of this void that the government does not argue that the claims at issue in this case were false because physician approval was absent in states where it was required; instead, the government focuses on the reimbursement inflation resulting from dispensing drug forms and dosages that were not medically necessary or economical. *See, e.g.*, Pls. Supp. 8, ECF No. 398 ("each claim form omitted information that directly impacted payment: that the drug was originally prescribed in a different dosage form or strength that could have been filled for much less money; and that the claim was submitted as part of a systematic switching scheme").

response brief, it rejected the theory outright. *United States v. Sanford-Brown Ltd*., 788 F.3d 696, 711-12 (7th Cir 2015) (*Sanford-Brown I*). This was a boon to Par, to the extent that it had cast the plaintiffs' legal theory as implied false certification, and the plaintiffs' response gave unduly short shrift to that new and controlling precedent from the Court of Appeals for this Circuit.[6]

But *Sanford-Brown I* was not long for this world; its core holding that there is no implied false certification theory of FCA liability was rejected by the Supreme Court only a year later in *Universal Health Services, Inc. v. United States and Massachusetts ex rel. Julio Escobar*, 136 S. Ct. 1989 (June 16, 2016) ("*Escobar*"). The Supreme Court expressly recognized in *Escobar* the viability of a theory of implied false certification in FCA cases "in some circumstances." *Id*. at 1999. Specifically, the Court held that "when . . . a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions *can* be a basis for liability *if* they render the defendant's representations misleading with respect to the goods or services provided." *Id*. (emphasis added). To embody

[6] *Sanford-Brown I* was decided about three-and-a-half weeks before the plaintiffs filed their response brief and seriously wounded their FCA claim. Disappointingly, and in a lapse the Court assumes was the product of inadvertence in the face of the advancing deadline for filing their brief, the plaintiffs both mischaracterized and failed to meaningfully engage with *Sanford-Brown I* in their response brief. *See* ECF No. 369. In a perplexing statement at page 35 of their brief, the plaintiffs assert that in *Sanford-Brown I*, "[t]he court found that compliance (or lack of compliance) with the regulations . . . had no direct impact on the amount of government payment, and thus was not actionable." The case said no such thing. The opinion did not discuss any distinction between regulatory violations that affect the amount of payment and those that do not, which may explain why the plaintiffs' brief includes only a general cite to the portion of the opinion that deals with the implied certification issue, rather than a pin cite to a page of the opinion where that purported holding is actually set forth. Had the Seventh Circuit actually said in *Sanford Brown I* that regulatory violations affecting the amount of payment sought from the government are actionable absent an express misstatement on the claim form, the government certainly would have featured that holding front and center in its response brief rather than burying it in a three-sentence paragraph more than 30 pages in. The plaintiffs' characterization is all the more perplexing because elsewhere they did, albeit haltingly in a footnote, acknowledge that *Sanford Brown I* rejected the implied certification theory, at least in cases not involving express "conditions of payment." Pl. Mem. 40 n.13, ECF No. 369. (As will be discussed, *Escobar* subsequently eliminated that potential distinction).

this principle, the Court set forth two conditions for an implied-certification claim: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those statements misleading half-truths." *Id*. at 2001. Addressing the concern of opening the flood gates to many more FCA claims by recognizing an implied falsity cause of action, the Court explained that its decision would keep claims appropriately cabined because the FCA still imposes "rigorous" requirements with respect to scienter and materiality. *Id*. at 2002.

*Escobar* was decided at the pleadings stage and did not address the question of whether *all* claims for payment "implicitly represent that the billing party is entitled to payment" because it was clear on the alleged facts of that case that the claimant did more than demand payment; it made certain representations about the services provided while omitting "critical qualifying information" about those services. *Id*. at 2000. Specifically, the mental health services facility in question was alleged to have violated the FCA by submitting reimbursement claims displaying codes for specific services provided by specific types of qualified professionals, when in fact services (such as counseling and the prescribing of medications) were provided by unlicensed or unqualified personnel. The Court held that the claims submitted were not simply demands for payment but also included representations about what kind of provider performed the treatments for which payment was sought. Thus the omitted information—that these providers were not appropriately trained and licensed to provide the treatment under Massachusetts Medicaid regulations—rendered those representations misleading half-truths, and therefore, "misrepresentations." 136 S. Ct. at 2000-2001.

*Escobar* changed the framework of this case, first, by vitiating Par's argument that no relief can be obtained under an implied false-certification theory in this Circuit. It also did away with Par's argument that *only* an undisclosed violation of "an express condition of payment" can be "material" the government's decision to pay a claim. *See, e.g.*, Par Mem. 19-23, ECF No. 359. The Court held, to the contrary, that "[w]hether a provision is labeled a condition of payment is relevant but not dispositive of the materiality inquiry." 136 S. Ct. at 2001. (Accordingly this Court does not address that argument of Par's any further.)

Despite these developments, the plaintiffs do not unabashedly embrace *Escobar* either. Having attempted to avoid primary reliance on a theory of implied false certification in their response brief (filed when *Sanford-Brown I* was good law), in their supplemental brief, the plaintiffs downplay the significance of *Escobar* to the element of falsity under their theory of the case, which they say is not one of implied false certification at all. The plaintiffs argue instead that the FCA is *per se* violated when a provider "overcharges" the government or "inflates" a claim by "select[ing] the more expensive treatment to increase government reimbursement, for no additional medical benefit to the patient." Pls. Resp. 2, ECF No. 269. The plaintiffs say it is obvious that the government was defrauded if Par "intentionally and systematically caused claims to be submitted and paid by Medicaid for Par's higher-reimbursed medications that offered no additional medical benefits than the dosage forms originally prescribed." USA Resp. 34, ECF No. 369. In other words, the plaintiffs assert that a facially accurate and non-misleading claim is nevertheless false or fraudulent within the meaning of the FCA if there are underlying regulatory violations with a direct nexus to the government's decision to pay the claim. As discussed immediately below, however, that is not what *Escobar* says. And prudently, the plaintiffs also argue that, alternatively, their claims survive under the implied false certification

theory. That battle is at least pitched on the correct field, but the outcome still favors the defendants.

**2. The Plaintiffs' "Direct Nexus" Theory of FCA Liability is Untenable**

The plaintiffs' argument that their case falls outside the implied false certification framework is unpersuasive. *See* Pls. Suppl. 1, ECF No. 398. In arguing that *Escobar* has no effect on their core argument, they essentially request strict liability on the premise that charging more than the lowest possible rate is by definition a false claim because doing so "directly affects payment." *Id*. at 6. The plaintiffs argue that, unlike here, implied certification was a necessary theory in *Escobar* because the regulatory violations in that case did not pertain to payment. *Id.* This argument is difficult to understand. The Court fails to see how this case is meaningfully different from the situation presented by *Escobar*, where violations of licensing regulations led to the provision of care for which *no* reimbursement should have been available. If that is not an "overcharge," what is?

Notably, the plaintiffs provide no authority for drawing this untenable distinction. Moreover, their broad interpretation of the FCA, under which liability arises whenever there is a "direct nexus" between a fraudulent scheme and inflated payments by the government, Resp. at 24, ECF No. 369, is inconsistent with *Escobar*, which expressly reiterated what the Court had said before: "The False Claims Act is not 'an all-purpose antifraud statute.'" 136 S. Ct. at 2003 (quoting *Allison Engine*, 553 U.S. at 672). "[E]ven when a relator can prove that a defendant engaged in fraudulent conduct affecting the government, FCA liability attaches only if that conduct resulted in the filing of a false claim for payment from the government." *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 57 (1st Cir. 2017) (affirming grant of summary judgment against relator who offered only aggregate data to connect a fraudulent scheme to bill

for off-label (non-FDA approved) uses of drugs to the submission of false claims) (internal quotation marks omitted). The *sine qua non* of an FCA claim is the submission of a claim that is actually false. *Id.* And as one court has explained, the "paradigmatic" false claim is "an incorrect description of the goods or services provided or a request for reimbursement for goods or services never provided." *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1031 (D.C. Cir. 2017) (citations omitted); *see also United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 779 (7th Cir. 2016) (identifying these forms of misdescription as causing claims to be false). Thus, to prove an FCA claim, a plaintiff "must show (1) that the defendant made a statement in order to receive money from the government; (2) that the statement was false; and (3) that the defendant knew the statement was false." *United States ex rel. Hanna v. City of Chicago*, 834 F.3d 775, 778 (7th Cir. 2016). As *Escobar* teaches, the effect that a representation has on the government's decision to pay a certain amount pertains to the issue of materiality, rather than the falsity of the claims themselves. 136 S. Ct. at 2002. The plaintiffs' "direct nexus" theory thus conflates two distinct elements of an FCA claim—falsity and materiality—into a single inquiry and in the process does away with the requirement of a false statement in connection with the claim.

Relying on *Marcus v. Hess*[7] and nonprecedential district court cases, the plaintiffs contend that "Courts have consistently held that a claim for payment that overcharges the

[7] *Hess*, of course, has been superseded by amendments to the statute. Indeed, it precipitated an amendment because, as the Seventh Circuit described, the case "held that a relator could bring a *qui tam* action based entirely upon information contained in an indictment to which he had contributed nothing." *United States v. Bank of Farmington*, 166 F.3d 853, 858 (7th Cir. 1999) *overruled by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). "Congress amended the statute to preclude actions 'based on evidence or information the government had when the action was brought.'" *Id.*

government, or charges for unnecessary services, is a false claim for purpose of the FCA without further inquiring whether the defendant violated a regulation or made a false certification." Pl. Mem. 24, ECF No. 369; Pl. Supp. 5, ECF No. 398. That is not an accurate characterization. In *Hess*, 317 U.S. 537 (1943), the Supreme Court held that the FCA applied in the context of a bid-rigging scheme that resulted in the submission of inflated claims because of the non-competitive nature of the bids. *Id.* at 543 ("The government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive."). "[E]very swollen estimate which was the basic cause for payment of every dollar paid by the [United States] into the joint fund for the benefit of respondents. The initial fraudulent action and every step thereafter taken, pressed ever to the ultimate goal—payment of government money to persons who had caused it to be defrauded." *Id*. at 543-44. The plaintiffs here say that *Hess* stands for the proposition that "a fraudulent demand which inherently causes the government to pay more than it should is a false claim under the FCA." But there is no such thing as "inherent" fraud; fraud requires a misrepresentation (whether affirmative or by omission). *U.S. ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 917 (7th Cir. 2005) ("fraud . . . requires more than breach of promise: fraud entails making a false representation").

*Hess*, which did not address this question, does not suggest otherwise. The Court did not rely on the "inherent" fraudulent nature of bid-rigging; it relied on the fact that the defendants had falsely implied that the bidding process was competitive. *See Hess*, 317 U.S. at 543 ("many if not most of the respondents certified that their bids were 'genuine and not sham or collusive.'); 539 n.1 (describing the collusive and "private" bidding scheme). In short, in *Hess*, the claims submitted were fraudulent because the Court determined that they misrepresented by omission

that the bidding process was fair. *See also United States ex rel. Blaum v. Triad Isotopes, Inc.*, 104 F. Supp. 3d 901, 915 (N.D. Ill. 2015) (bid-rigging is a form of fraudulent inducement).

Thus, restraining competition in a competitive bidding process is fraudulent not because it "inherently" raises costs, but because it involves a representation that there was competition when in fact there was none. It is simply not true that the *Hess* Court did not care "whether the defendant violated a regulation or made a false certification." Under current law, *Hess* would be considered an implied false certification case: the defendants misled the government by the implication or certification that bidding competition occurred when in reality the process was rigged. *Escobar* provides the framework for the evaluation of such claims.

The plaintiffs' "direct nexus" theory, moreover, has no support in precedent from this circuit and it is inconsistent with cases like *Thulin v. Shopko Stores Operating Co., LLC*, 771 F.3d 994, 999–1000 (7th Cir. 2014), where the Seventh Circuit affirmed the dismissal of FCA claims concerning a scheme to overcharge Medicaid by billing Medicare at rates higher than those paid to private insurers for the same drugs. In *Thulin*, as here, the claim was that pharmacies systematically exploited price differentials to maximize their reimbursement from Medicaid, but the Court of Appeals rejected the argument because, notwithstanding the fact that Medicaid was overcharged by the scheme, there was no basis to conclude that any false information had been included with the reimbursement claims and the defendant "was not obligated to inform Medicaid of [the lower rates] and was permitted to bill in the fashion that it did." 771 F.3d at 999. *See also, e.g., U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 709–10 (7th Cir. 2014) (overpayment for services did not give rise to FCA liability; "a 'diminished value' of services theory" does not give rise to an FCA claim). *Thulin*'s rationale (which the plaintiffs ignore in favor of non-binding and largely pre-*Escobar* authority)

cannot be squared with the plaintiffs' "direct nexus" theory that anything that inflates the reimbursement amount, causing unnecessary overpayment, is actionable as a "false claim." *See* Pls. Mem. 24-26, ECF No. 369.

The "anything" matters—for example, using a false AWP, as in *United States ex rel. Ven-A-Care v. Actavis Mid Atlantic LLC*, 659 F. Supp. 2d 262, 271 (D. Mass. 2009). The AWP capped reimbursements in this case, too, but here, unlike in *Ven-A-Care*, the plaintiffs do not allege that the pharmacies or Par falsified the AWP or in any other way billed more for Par's drugs than the Medicaid regulations allowed. Cases cited by the plaintiffs regarding "up coding" or "up charging" similarly miss the mark. Again, the falsity in such cases relates directly to information represented on the claim form: *e.g.*, that a certain type of provider performed expensive services when he or she had not, or performed services that were not medically indicated. The mere existence of a treatment with a lower reimbursement rate, in itself, does not equate with a false claim, no matter what other law or regulation it might violate to provide the more expensive one. Had the plaintiffs any binding authority for their contrary proposition, certainly they would have highlighted it.

Notwithstanding their advocacy for a "direct nexus" theory of false claim liability, the plaintiffs have consistently framed their claims in a way that cannot be meaningfully differentiated from the implied false certification theory. The plaintiffs alleged in their complaints and continue to contend that Par caused the pharmacies to submit claims for reimbursement, which, while facially truthful with respect to the goods provided and their cost, were false because the pharmacies had omitted the information that: (i) they had substituted forms or dosages to maximize their profit; (ii) they had violated requirements that drugs to be provided "economically"— *i.e.*, at the lowest cost to Medicaid, according to the plaintiffs; and

(iii) the switch was not "medically necessary." The fraudulent, or false, nature of the claims results from the omission of information that is allegedly necessary to make the statement set forth on the claim (essentially, "PHARMACY paid $X for Drug Y which was dispensed to Customer Z on DATE") not misleading. That claim is therefore "fraudulent" only by its alleged implication that it was proper under the Medicaid regulations to dispense Drug Y to Patient Z. The falsity, if any, lies only in the omission of information that would render the representations about the dispensed drugs (the "goods or services provided") misleading. *See* Pls. Resp. 38, ECF No. 369. ("The point is that the fields that do exist on the claim forms, including National Drug Codes ("NDCs") identifying the Par Subject Drug, should not have been filled in with a Par Subject Drug at all, as that choice was not medically necessary or economical."). Thus, *Escobar* provides the appropriate legal framework for assessing the merits of Par's summary-judgment motions on the FCA claims.

**3. Under *Escobar* the Claims at Issue Are Not Impliedly "False"**

Careful not to put all their eggs in their "direct nexus" basket, the plaintiffs argue that even if the *Escobar* test applies, their claims succeed under an implied false certification theory, too. Under *Escobar*, the two conditions for an implied-certification claim are that, "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those statements misleading half-truths." 136 S. Ct. at 2001.

The plaintiffs first contend that the claim forms contained misleading half-truths because they set forth the drug dispensed and the dosage form and strength but omitted the critical information that "directly impacted payment," namely that "the drug was originally prescribed in

a different dosage form or strength that could have been filled for much less money; and that the claim was submitted as part of a systematic switching scheme, the purpose of which was to bill the government for more money in direct violation of specific regulations requiring providers to provide only goods and services that are 'economical' and 'medically necessary.'" Pl. Supp. 8, ECF No. 398. Second, the omission was material because it "went to the heart of the government's bargain" and any reasonable person would attach importance to the facts that lower-cost drugs were available, that the switch was done with a profit motive, and that the switch had been, at best, only superficially approved by a physician. *Id*. at 11.

Unsurprisingly, even though Par now acknowledges the implied-false-certification theory as valid, it contends that the case against it fails the Supreme Court's two-part test as a matter of law. First, it contends that the claim forms were facially truthful and that no representations were made at all beyond the accurate statement of what drug was dispensed and the amount owed, as set by the Medicaid agencies themselves. Par Suppl. 6, ECF No. 399. Par argues that the description of the drug dispensed is not a representation of compliance with any statutory requirements, nor does it represent that the drug dispensed is the one originally prescribed. It further contends that any representations on the claim form were not rendered misleading by the pharmacies' omission information that they had no obligation, under the regulations, to provide. Par also argues that the record is devoid of evidence that any misrepresentation was material to the government's decision to pay the claims.

Par submitted further supplemental authority after *Escobar*. When the Supreme Court remanded the *Sanford-Brown* case (which had rejected the implied false certification theory) to the Seventh Circuit for reconsideration in light of *Escobar*, the Court of Appeals once again affirmed the judgment against the relator. *United States v. Sanford–Brown, Ltd.*, 840 F.3d 445

(7th Cir. 2016) ("*Sanford-Brown II*"). The relator had claimed that his former employer, Sanford-Brown College and its corporate parents, submitted claims certifying compliance with all applicable laws and regulations when in fact they had "violated provisions that: i) prohibited them from paying incentive compensation to certain types of employees involved in admissions and recruiting; ii) required them to maintain accreditation; iii) required them to refund to the U.S. Department of Education portions of Title IV funds for certain students who failed to complete at least 60% of a term; iv) prohibited them from harassing students to attend class; v) required students who received Title IV funds to maintain a minimum GPA or other adequate progress towards graduation; and vi) prevented them from admitting students with remedial needs into accelerated programs." *United States v. Sanford-Brown, Ltd*., 788 F.3d 696, 702 (7th Cir. 2015).

Applying the new rule of *Escobar*, the Seventh Circuit concluded that the relator failed to establish either condition for a successful implied false certification claim. *Sanford–Brown II*, 840 F.3d at 447. First, there was no proof that *any* representations were made in connection with the claims for payment; in other words, the defendants did nothing more than request a disbursement. Second, the relator "offered no evidence that the government's decision to pay SBC would likely or actually have been different had it known of SBC's alleged noncompliance with Title IV regulations"; and indeed, the payer-agency had already examined SBC's practices multiple times and declined to impose any penalties. *Id*. (citing *Escobar*, 136 S.Ct. at 2003 for the proposition that a representation is unlikely to be material where the government pays claims with actual knowledge of regulatory violations). This discussion in *Sanford-Brown II*, though brief, is highly instructive as to how *Escobar* applies in this case.

### a. Representations About the Goods or Services Provided

The first question is what "specific representations about the goods and services provided," if any, were made in the claims the pharmacies submitted for reimbursement for dispensing Par's subject drugs. The Supreme Court did not elucidate what it meant by a "specific representation about the goods and services provided," and as noted above, it expressly deferred the question "whether all claims implicitly represent that the billing party is *legally entitled* to payment." *Escobar*, 136 S. Ct. at 2000 (emphasis added). But by way of example, in *Escobar*, the facility "used payment codes corresponding to different services [than] its staff provided," and represented by way of National Provider Identification numbers that qualified practitioners had provided the services, when in fact they lacked the credentials and licensing required by law. 136 S. Ct. at 1997. Therefore, the claim forms had made "specific representations about the goods and services provided," *i.e.*, the codes corresponding to the service and the provider. In *Escobar*, inclusion of the provider identification numbers meant that the claims effectively stated: "for these specific services rendered by this kind of licensed professional, X amount is due." Therefore, the claims did "more than merely demand payment." *Id*. at 2000.

So too in *Presser*. In that case (also on review of a motion to dismiss), the Seventh Circuit concluded that the claims at issue represented, by way of a billing code on the forms, that a "full psychological assessment[] by a therapist or an evaluation by a psychiatrist" had taken place. In reality, the facility had discontinued psychiatric evaluations; furthermore, the code was used by practitioners unqualified to perform the designated service. The Seventh Circuit concluded that because the clinic billed Medicaid "for a completely different treatment" than what was provided, the claims made *express* false statements, not just representations rendered misleading by the omission of material information. 836 F.3d at 779. Although the Court of

Appeals did not treat it as an implied false certification case *per se*, *Presser* does elucidate the Court's view of what is meant by a "specific representation" under *Escobar*. As in *Escobar*, the court looked not merely the existence of a claim for payment, but a representation about a ***good or service provided*** in connection with the claim. Only after identifying such a representation—the billing codes—did the court go on to evaluate whether that representation was a false statement, expressly or implicitly.

By contrast, a simple demand for payment does not constitute a "specific representation about the goods and services provided." In *Sanford Brown II*, the Seventh Circuit reaffirmed the denial of the plaintiff-relator's summary judgment motion where he had "offered no evidence that defendant Sanford Brown College (SBC) made any representations at all *in connection with its claims for payment*." 840 F.3d at 447 (emphasis added). In other words, the "claims for payment" were not *themselves* "specific representations." Even if the issue was simply the plaintiff-relator's failure to meet the burden of proof, the quoted statement makes clear that an unadorned claim for payment is distinct from the "specific representation about the goods or services provided" that *Escobar* requires.

In this case, the plaintiffs do not identify with precision any "specific representation" that they claim was rendered a misleading half-truth by the omission of material facts. The closest they come to pinning down a specific "representation" is to point to information on the claim forms "including" the National Drug Codes. Pls. Resp. 38, ECF No. 369. The vague usage of "including" is at odds with *Escobar*'s call to identify "specific" representations that implicitly render a claim false, and the plaintiffs compound the problem when they argue that the claim forms were misleading half-truths because they described the goods provided without providing "critical information about their material noncompliance with certain statutory and regulatory

requirements." Pls. Suppl. 8, ECF No. 398. Each claim form, they maintain, "omitted information that directly impacted payment: that the drug was originally prescribed in a different dosage form or strength that could have been filled for much less money; and that the claim was submitted as part of a systematic switching scheme, the purpose of which was to bill the government for more money in direct violation of specific regulations requiring providers to provide only goods and services that are 'economical' and 'medically necessary.'" *Id*. Thus, it is clear that the plaintiffs are primarily concerned with the whether it was permissible to dispense the subject drugs at all, not with whether there was a false representation about the drugs, their cost, or the quantity dispensed.

That is a non-starter. Before *Escobar*, it was clear in this circuit that "it is not enough to . . . prove that the pharmacy engaged in a practice that violated a federal regulation" because "***[v]iolating a federal regulation is not synonymous with filing a false claim***." *United States ex rel. Grenadyor v. Ukrainian Village Pharmacy, Inc*., 772 F.3d 1102 (7th Cir. 2014) (emphasis added); *see also United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 858 (7th Cir. 2006). In *Crews*, the defendant submitted vouchers to the Department of Public Aid for payment for drugs distributed to Medicaid patients; the dispensing of the drugs was "akin to alleging the double-billing of the IDPA (and Medicaid) for drugs" because returned drugs were (allegedly) redispensed and billed again by virtue of the defendants' violations of numerous regulations related to the storage and handling of the pills. Notwithstanding the potential for double billing, these violations did not render the vouchers false claims because a voucher "[did] not turn into a false claim under the FCA just because NCS stored or handled the drugs improperly." 460 F.3d at 858. There is no reason to think that *Escobar* changed this principle somehow—to the contrary, it expressly declined to address it.

The government's emphasis on the fact that, here, the regulatory violations directly affected the payment amount does not make the claims at issue in this case any more "false" than the ones addressed by the Seventh Circuit in *Grenadyor* and *Crews*. In *Grenadyor*, the Seventh Circuit distinguished between a false claim and an unauthorized billing—something that would, of course, "directly affect" the amount paid by Medicaid—and concluded that they are not the same thing. 772 F.3d at 1005. *Presser* reaffirmed that this proposition retains its vitality post-*Escobar*. Even assuming violations of the "medically necessary" and "economical" regulations in this case, those violations might lead to "unauthorized billing," but they do not, without some "specific representation," make the submitted claims "false."

In this case, the claim forms, by law, are standardized; the federal and state agencies require the same information and certification on their forms. Notably, that information does ***not*** include any affirmation or statement that the claimant has complied with all applicable laws and regulations.[8] Generally, the claim forms require certification by the pharmacy (or the prescriber) that the form contains "true, accurate, and complete" information and that the pharmacy

[8] It is true that as a condition of *enrollment* in the Medicaid program, the pharmacies were required to certify that they would follow all applicable laws and regulations. But the enrollment paperwork on which this certification is made is not a claim for payment and is not the subject of the FCA claims here; the *reimbursement forms* are alleged to contain the actionable false representations. True, an FCA claim can be premised on a two-step certification, such as when a as a condition of participation in a government-reimbursement program, some promise is made, and then a facially accurate claim is submitted after that promise has been violated. *See Main*, 426 F.3d at 916 (explaining that a false statement "integral to the causal chain leading to payment" can lead to liability even if the federal bureaucracy "apportion[s] the statements among layers of paperwork."). In such cases, a participant in a federal funding program may be subject to liability if, ***at the time of enrollment***, that participant certified that it would comply with pertinent laws or regulations despite having no intention to do so. *Id.* at 917; *Grenadyor*, 772 F.3d at 1105. But if the defendant intended to comply at the time of enrollment, but later did not, it has not committed fraud; it has breached a contract. *See Main*, 426 F.3d at 917 ("A university that accepts federal funds that are contingent on following a regulation, which it then violates, has broken a contract" and not committed an "actionable fraud.").

Here, the plaintiffs do not advance a theory of fraudulent inducement.

"understand[s] that any payment made in satisfaction of this claim will be derived from federal and state funds and that any false claims, statements, or documents, or concealment of material fact may be subject to prosecution."[9] See Pl. Response SOF ¶ 51, ECF No. 370; Pls. Mem. 3, ECF No. 369.

If the statements in the certification block constitute "specific representations about the goods or services provided" at all, none of them are the focus of the plaintiffs' arguments, which rest instead on the inflated cost of drugs that the plaintiffs say should not have been dispensed at all. The plaintiffs do argue that "[t]he claim forms [require] the provider to certify that it has told the entire truth and concealed nothing material about its claim from the government." Pls. Mem. 39, ECF No. 369; *see also* p. 45 ("the providers falsely certified in the claim forms themselves that they were telling the whole truth."). But whether the pharmacies told the whole truth—everything the FCA would require—is the entire question that is raised by Par's motions targeting the element of falsity, *i.e.*, whether the providers falsely implied anything about the goods or services provided or were required to provide more information.

**b. Representations as Misleading "Half Truths"**

Absent any specific misrepresentation on the face of the claims, the plaintiffs must identify omitted information that renders the description of the dispensed drugs misleading. According to the plaintiffs, two things were omitted that directly impacted the payment: "that the drug was originally prescribed in a different dosage form or strength that could have been filled for much less money" and that "the claim was submitted as part of a systemic switching scheme, the purpose of which was to bill the government for more money in direct violation of the

[9] Again, Par does not take issue with the plaintiffs' characterizations of the standard certifications that appear on claim forms, and neither party asks the Court to focus on any distinctions in wording among the federal and various states governments' claim forms.

specific regulations requiring providers to provide only goods and services that are "economical" and "medically necessary."

There is little basis to infer that a pharmacy's Medicaid reimbursement claim constitutes a representation that the drug for which reimbursement is sought was the drug originally prescribed for the patient. For starters, the claim form does not require the reporting of any information about the form or dosage originally prescribed—only what was actually dispensed. Nor does it require confirmation that the drug dispensed was the lowest cost alternative available in the market—just the government's reimbursement rate for the drug that was provided. That the government claim forms do not require the submission of this information suggests that its omission does not render the provision of the required information misleading. In *Thulin*, for example, the Seventh Circuit considered and rejected FCA claims based on reimbursement forms that did not require information about whether the patient was subject to a dual-copay, finding the absence of a request for such data on the claim form to be "compelling evidence" that the defendants "did not have an obligation to submit co-pay information to Medicaid. If they did, one would think that such an obligation would have been incorporated into the billing protocol that they were legally required to use." 771 F.3d at 1000. If pharmacies were required to identify whether the drug dispensed was the drug originally prescribed, one would expect that the Medicaid agencies would require them to say so on their reimbursement forms. But they don't.

"Omissions are actionable as implied representations when the circumstances are such that a failure to communicate a fact induces a belief in its opposite." *Midwest Commerce Banking Co. v. Elkhart City Ctr.*, 4 F.3d 521, 524 (7th Cir. 1993). Here, the claims at issue provide no basis to infer that the drug dispensed was the drug originally prescribed. As Par points out, given the plethora of state laws and regulations that govern the dispensing of

prescription medications, there may be many reasons why the drug actually dispensed may differ from the drug originally prescribed. Dosage strength and form substitution are permitted upon authorization of the prescribing physician, and there may be a variety of reasons pharmacies seek such authorization, ranging from patient preferences for one form over another (*e.g.*, tablets versus capsules), promoting patient compliance with medication regimens by minimizing the need to split doses or reducing the number of required doses to pharmacy inventory constraints. See Par. SMF ¶¶ 9-11, ECF No. 364. And under some circumstances, state laws require substitution of generic drugs where such substitution would lower the price of the drug. *See, e.g.* Ind. Code § 16-42-22-10(a) (1999). In short, the possibility that the drug dispensed differs in some fashion from the drug prescribed is pervasive; it exists for virtually every transaction between pharmacy and patient. In that light, a pharmacy's reimbursement claim cannot reasonably be read as an affirmation that the drug for which reimbursement is claimed was the drug originally prescribed and a pharmacy does not commit fraud by failing to affirmatively report such substitutions when they occur. And, again, how would they make such reports when the form required by state and federal Medicaid agencies does not even seek that information?[10]

[10] The plaintiffs identify no authority supporting their theory that simply listing the drug dispensed implies that it was the precise form and dosage strength originally prescribed. They might have cited, but did not, *Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust v. Walgreens Company*, 631 F.3d 436 (7th Cir. 2011), which addressed a fraud claim in the context of the very prescription-switching activity that is the subject of this case. Drawing from the existing *qui tam* action against Walgreens, a third party payer ("TPP") (in this case, the functional equivalent of Medicaid) sued Walgreens under the Illinois Consumer Fraud and Deceptive Business Practices Act (ICFA), arguing that it had overcharged the TPP by filling prescriptions for ranitidine and fluoxetine with Par's more expensive forms of those generics. As summarized by the Seventh Circuit, "Each time it filled a prescription, the theory goes, Walgreens represented to the [pharmacy benefits manager, a middleman in the transaction] that it had received a prescription for the costly form of the drug; the PBM passed on the misrepresentation to Pirelli, who then reimbursed Walgreens at the more expensive AWP price." *Id*. at 439. On review from the granting of a motion to dismiss, the appellate court described the complaint as alleging that "Walgreens unlawfully and intentionally concealed from Pirelli's

As to the failure to disclose the existence of a profit-driven switching scheme that violates the medically necessary and economical treatment regulations, there is no basis to infer that the submission of a reimbursement claim includes an implied representation that the drug dispensed was the lowest-cost drug available that could adequately address the patient's needs. Even granting for the sake of argument that the regulations require providers to assure that treatment services provided are the lowest cost available, that is a far cry from a requirement that they ***certify*** that the treatment they provided was in fact the lowest cost available. How could they? What the plaintiffs posit is, in the context of pharmacies dispensing drugs to thousands of patients each day, and where reimbursement rates vary from state to state and are subject to frequent changes, and where the pharmacies' purchases of inventory may precede the dispensing of drugs by weeks or months, a practical impossibility. Pharmacies do not set Medicaid reimbursement rates and have no control over them; "[w]hether a particular drug is the dosage form with the lowest Medicaid reimbursement on the market at any given time is subject to the discretion of the state Medicaid agency, not that of the pharmacy." Def. Suppl, 8, ECF No. 399. They cannot be expected to stock the drug that may have the lowest reimbursement cost at any given point in time, and so there can be no expectation, much less implicit certification, that the

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PBM, or misrepresented to it, the form of the drug that was prescribed," and then stated: "That is fraud predicated on either a misrepresentation or omission." *Id*. (emphasis added); *see also id*. at 446 ("[T]he practices alleged in Pirelli's complaint constitute fraudulent activity.").

The Seventh Circuit took as true the assertions quoted above, but this Court must rely on proofs. *Pirelli* says nothing about how the pharmacies communicated a representation about "the form of the drug that was prescribed"; the Court simply stated that the "theory" of the case was that "fill[ing] a prescription" was a representation. *See* 631 F.3d 439. This Court consulted the complaint in *Pirelli*, too, and could find no description of how, as a factual matter, the pharmacy allegedly made a false representation or omission about the drug prescribed. Here, by contrast, we have claim forms that represent what drug was dispensed, and the very question is whether that statement is an implication about the particular form and dosage strength prescribed. As the plaintiffs evidently recognized (they do not cite *Pirelli* for this proposition), that question was not resolved by *Pirelli*.

drug actually dispensed carried the lowest reimbursement cap. The point is not that Medicaid regulations don't require the provision of the lowest cost treatment that is adequate for the patient's needs, but only that a drug reimbursement claim cannot reasonably be construed as a representation by the provider about the relative cost of the drug dispensed to other drugs that were also available options.

This is all the more apparent considering that the reimbursement claims in no way concealed that the drugs dispensed were covered by higher reimbursement rates than other variations. The FLUs and MACs are set by the Medicaid agencies, not by the pharmacies; the agencies therefore know which drugs are subject to those caps and which are not. The reimbursement claim forms neither include nor omit information in a manner that could mislead the agencies about the reimbursement rate applicable to the drug dispensed. Indeed, and as discussed further below, in arguing that the reimbursement claim forms were misleading, the plaintiffs effectively concede that dispensing Par's drugs was sometimes legitimate; the argument that the reimbursement claims were misleading rests on the premise that the agencies could not from the claims themselves discern the legitimate from the illegitimate. Had they all been illegitimate, it would have been enough that they claimed reimbursement for Par's drugs.

Undressed, the plaintiffs' argument is simply that the pharmacies never should have dispensed the subject drugs, and to the extent that they did, they were required to self-report regulatory violations so that Medicaid would not be misled into paying them. That argument is precluded by the case law above holding that violating underlying regulations (an "unauthorized billing") is not the equivalent of filing a false claim. Omitting information from the claim form about the course of events that led to the dispensing of a particular drug, or about its relative cost, does not go to the truth or falsity of the representations on the claim form itself, which, as noted

above, is limited to the claim for payment, at the government-set rate, for the actual drug dispensed. The undisclosed regulatory violations do not render those factual statements misleading.

Contrast this case with *Escobar* and *Presser*. The implied and express misrepresentations in those cases went directly to the truth of what was on the claim forms—whether the listed treatment was provided at all or whether the treatment was inaccurately described (by way of material omission). In *Escobar*, it was false to claim reimbursement under a specific code for counseling services because (as the claim forms failed to disclose), the practitioners who performed those services were unqualified and unlicensed. Therefore, the use of the provider code was an implied representation that the service prescribed by that code had been performed; and billing under that code amounted to an implied false statement by omission about the service provided. Similarly in *Presser*, it was not true that psychiatric evaluations had been provided because, well, they had not been provided. Here, by contrast, whether or not underlying Medicaid regulations had been violated by the dosage-form substitutions, the truth of the information on the claim forms is not implicated. What the plaintiffs are really saying is that the claim itself misrepresents that the pharmacy is legally entitled to payment, not that there is anything on the claim form that is false expressly or by implication.

But that is where the Supreme Court stopped short in *Escobar* and the Seventh Circuit would not go in *Sanford Brown II*. If the submission of a claim is construed to imply that the submitter is entitled under the applicable regulatory regime to payment of the claim, then both *Sanford Brown II* and *Presser* would have to have been decided differently. But both cases rejected the notion that submitting a claim equates with representing a legal entitlement to payment, leaving us with what the Supreme Court did endorse in *Escobar*: omissions can be a

basis for liability if they render the defendant's representations misleading "*with respect to the goods or services provided*." 136 S. Ct. at 1031 (emphasis added). The FCA "focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme." *United States ex rel. Kelly v. Serco, Inc*., 846 F.3d 325, 333 (9th Cir. 2017) (quoting *United States ex rel. Aflatooni v. Kitsap Phys. Serv*., 314 F.3d , 1002 (9th Cir. 2002)). The pharmacies here sought payment for the goods they provided. Where the claim is facially accurate about the treatment provided (unlike in *Escobar* or *Presser*), the question of whether other dosages or forms *should have been* provided, *see* Pls. Mem. 38, ECF No. 369, pursuant to various Medicaid requirements, or whether they took part in a "menacing underlying scheme" with Par, is different.

In essence, even assuming that the pharmacies violated Medicaid regulations pertaining to physician authorization, medical necessity, or economical treatment, the government at most can establish on this record that the violations occurred. That's a compliance issue, not evidence of the falsity of claims for payment; it is a violation of a statutory and regulatory scheme that carries its own penalties for violations, as Par points out in connection with its materiality arguments. *See Kelly*, 846 F.3d at 333 (explaining that there must be an actual claim at issue, not merely a scheme). If the government overpaid in these cases, it was not because the claim form misled them about what drugs had been prescribed. If substituting drug forms and dosage strengths is unlawful it is made so by Medicaid law[11] and might give rise to liability and penalties under other provisions of law. But the FCA is not a blunderbuss to assure the enforcement of regulations requiring the provision of only medically necessary treatment in an

[11] *See, e.g*., 42 U.S.C. § 1320c-5, which creates a remedial administrative process for noncompliance with Medicaid regulations. The primary penalty is exclusion from the program—catastrophic in the case of national pharmacy chains.

economical manner. Unlike the defendants in *Escobar* and *Presser*, the pharmacies did not expressly or impliedly mislead the government about what they provided or how much it cost. Instead, as in *Sanford-Brown II*, all the plaintiffs have shown is that the pharmacies submitted bills, which are not in themselves declarations of legal entitlement to payment.[12]

**c. Materiality**

Even if this Court had concluded that the claims at issue were false, the question would remain whether the omitted information (the substitution and the alleged regulatory violations) was material to the government's decision to pay.

The government contends that any misrepresentation that inflates the amount charged to the government is material. Although the mere fact of overpayment boosts the case for materiality, post-*Escobar* this kind of *per se* conclusion is untenable; the Supreme Court expressly prescribed a holistic, fact-based approach to determining materiality. Par believes it is entitled to judgment under that approach, although it places special emphasis on a single factor—that the asserted violations were not "conditions of payment." Relatedly, it argues that Medicaid has its own enforcement scheme, strongly implying that non-payment of reimbursement claims is not the remedy for regulatory violations, and that the repeated payments of the claims at issue suggests a lack of materiality.

This Court need not decide the materiality question in light of its conclusion that the claims were not false within the meaning of the FCA as interpreted by *Escobar*. But, even

[12] If they were, the burden of overseeing Medicaid compliance would shift from the government sponsors to the providers under a system of mandatory self-reporting. Providers, of course, must remain apprised of current regulations, but the plaintiffs do not explain what basis there is to require self-reporting of regulatory violations; and despite the government's best efforts, the FCA itself cannot be stretched to impose this requirement.

without this holding, materiality is a fact issue that the parties effectively put into dispute, and this Court could not decide the facts pertinent to materiality on the summary-judgment record.

### B. The Plaintiffs Failed to Adduce Evidence of Specific False Claims

Even if the premise of the plaintiffs' position—that claims seeking reimbursement for drugs dispensed due to Par's prescription-switching scheme constitute false claims under the FCA—is accepted for the sake of argument, their FCA cause of action would still fall short on this record because the plaintiffs have failed to proffer evidence that any particular claim was, in fact, the product of that scheme. As noted already, the starting point for proof of an FCA violation is the existence of a false statement used to obtain money from the government.

Par maintains, and the summary judgment record reflects, that the plaintiffs have failed to identify even one specific claim for reimbursement for a drug that was unlawfully switched—that is, dispensed without an original prescription or physician approval for a substitution, and in violation of regulations requiring all treatment to be medically necessary and economical. The plaintiffs have identified the whole universe of claims in the relevant time period where one of the subject drugs was dispensed, and the increased marginal cost to the government of the subject drug. But what they have not shown for any specific claim is that (1) the dispensed Par drug was in fact a substitute for a different drug; (2) if it was, the substitution was unauthorized; (3) the treatment was not medically necessary within the meaning of the federal or State Medicaid regulation applicable to that claim; or (4) the subject drug was not economical or cost-effective within the meaning of the applicable regulation. The plaintiffs instead appear to assume that *every* time a subject drug was dispensed during the relevant time period, it was because the pharmacy unlawfully (under plaintiffs' theory) switched a less expensive drug to a subject drug. Thus they contend that they in fact "point to over a million false claims." Pl. Mem. 2, ECF No.

369. This unsupported argument does not claim to answer the question whether it has evidence that each of those million claims demonstrably violated the regulations on physician approval, medical necessity, and cost-effectiveness. *See also id*. at 17 ("Walgreens and Omnicare submitted hundreds of thousands of false claims to the Medicaid program."); Pl. Additional SMF ¶ 53, ECF No. 371 (disputed by Par).

Par also notes that the subject drugs were, at times, subject to reimbursement caps that were lower than those applicable to the more standard forms and dosages, and that claims submitted in those circumstances would not give rise to liability even if the evidence established that drug substitution had occurred unlawfully (that is, violation of governing Medicaid law). And sometimes, the subject drug was originally prescribed, in which case no switching occurred at all. Rather than rebutting these points by pointing to other specific claims where neither of these things was true, the plaintiffs essentially concede the argument by explaining that they are not seeking to recover for such claims; they are not included in the universe of "false" claims the plaintiffs have defined. See Pls. Add'l SMF ¶¶ 74-75, ECF No. 371. The acknowledgement that their FCA claim does not encompass occasions when Par's drug was originally prescribed, or when the reimbursement cap applicable to Par's drug was actually lower, might streamline the case were it to advance to a stage at which a damage computation was required. But the plaintiffs' concession that there are tens of thousands of exceptions to their theory of liability[13] does nothing to remedy their failure to identify even one claim containing the implicit representations the plaintiffs allege were false. Simply put: Where is a specific reimbursement

[13] "Tens of thousands" is a fair characterization given the plaintiffs' concession that something on the order of 10 percent of reimbursement claims based on Par's drugs were subject to lower reimbursement caps. Pls. Add'l SMF ¶ 74, ECF No. 371. And this says nothing of the number of occasions when Par's drugs were originally prescribed or a substitution was authorized for a legitimate medical reason.

claim as to which the plaintiffs have adduced sufficient evidence to support a jury's reasonable determination that a pharmacy sought reimbursement for dispensing a subject drug that it had substituted for another, without physician approval, and where the subject drug was neither medically necessary nor cost effective?

There is none. Instead, the plaintiffs turn the burden of proof inside out. They need not affirmatively demonstrate falsity on a claim-by-claim basis, their thinking goes, so long as they can show that, for example, "there is no evidence that Walgreens pharmacists actually sought physician approval every time, or even most of the time." Pls. Mem. 9, ECF No. 369. It is the plaintiffs' burden to show that there was at least one drug reimbursement claim submitted that was false (according to their own definition of falsity), not Par's burden to show that every time a subject drug was dispensed, all regulatory requirements were satisfied. *Crews,* 460 F.3d at 857 (rejecting argument that difficulty proving element of offense due to defendant's lack of records justified shifting burden of proof to defendant; argument that defendant was required to prove lawfulness of its claims "defies common sense and the plain language of the FCA"). The plaintiffs confess the nonspecific nature of their evidence in arguing that "*All* claims for Par Subject Drugs that caused government losses are recoverable under the FCA because they were the result of Par's scheme to induce the submission of claims for more costly dosage forms and strengths, for no medical benefit." Pls. Mem. 35 n.12, ECF No. 369 (emphasis in original). There is no support for the proposition that "all" claims causing losses were a product of the scheme.

The plaintiffs have, to be sure, marshaled substantial evidence suggesting that Par worked closely with Walgreens and Omnicare to maximize their mutual profit by switching prescriptions to Par's drugs to exploit a loophole in the mechanism for regulating drug reimbursement cost. There is competing evidence about the pharmacies' efforts to secure physician authorization for

drug switching generally, and were that the issue, Par's motion would have to be denied. But the issue here is not whether the pharmacies ***always*** had authorization to switch to Par's drugs, but whether the plaintiffs have adduced evidence that any particular claim, or claims, falsely represented that a physician had authorized the dispensing of the drug for which reimbursement was claimed. Even if it seems statistically a near certainty that the pharmacies did not always have physician authorization to switch to Par's drugs, it remains incumbent on the plaintiffs to prove that they submitted at least one specific claim that was false. But they haven't done so. The plaintiffs' contention that its burden to demonstrate the falsity of each claim is relevant only to proving damages, *see* Pls. Mem. 35 n.12, ECF No. 369, is a dodge; they well know that a crucial element of their FCA claim is that a pharmacy submitted a false claim.

It should have been easy enough, at the summary judgment stage and after years of discovery, for the plaintiffs to meet their burden to identify and prove specific false claims. But they have failed to adduce the evidence necessary even to create a fact dispute about the bona fides of a single specific claim. The plaintiffs have not identified any claim for reimbursement where Par's drug was not the originally prescribed drug. They have not presented testimony from a single physician with respect to why he or she prescribed Par's drug or authorized a switch to Par's drug. They have not established that in any instance, a subject drug was not medically necessary. They have not shown that the subject drugs were not economical within the meaning of the relevant jurisdiction's laws (not every jurisdiction requires a pharmacy to dispense only the lowest-cost drug). (Indeed, the plaintiffs do not address anywhere the variance in the proof needed to demonstrate regulatory violations in all of the different jurisdictions in which claims were made.) What they have established is that a reasonable jury could conclude that Par and the

pharmacies made significantly more money by switching prescriptions from drugs with lower costs to Medicaid to Par's drugs.

That is not good enough. The Seventh Circuit has repeatedly jettisoned FCA claims that failed to identify specifically any false claim submitted to the government. In *Crews*, for example, the Seventh Circuit affirmed a grant of summary judgment in favor of the defendant pharmacies which were alleged, among other things, to have double-billed state and federal agencies for drugs dispensed to patients where the plaintiffs failed to prove that any specific claim was in fact a second bill for the same drugs. 460 F.3d at 857. In so holding, the Court of Appeals rejected the notion, expressly advanced by the plaintiffs in this case, that the statistical likelihood that false claims were submitted would suffice to satisfy the plaintiff's burden to prove that at least one specific false claim was submitted. *Id*.; *see also* Pls. Resp. 35 n.12, ECF No. 369. It is not enough to say "given this scheme, surely there were false claims submitted"; the plaintiff is required to prove that to be the case.[14] *Grenadyor* provides another illustration of the point. There, the Seventh Circuit reaffirmed that proof that a pharmacy had regularly provided kickbacks to customers failed to state a claim under the FCA where the plaintiffs had failed to identify even a single specific claim submitted for reimbursement for drugs dispensed to a patient that had received a kickback. 772 F.3d at 1107. Even though the scheme violated

[14] None of the cases cited by the plaintiffs in support of statistical sampling stand for the proposition that a plaintiff may dispense with proof of some actually false claim in favor of an inference drawn from the statistical likelihood that any particular claim was false. In *Rogan*, the Seventh Circuit did reject the idea that the trial judge was required to make a finding of falsity as to every individual claim at issue, noting that "[s]tatistical analysis should suffice." And so it should. But to do statistical sampling, there must be statistically reliable proof of the frequency of false claims in the sample; that is, proof that some portion of a statistically relevant sample of claims are actually false. Statistical sampling can of course be used to provide an estimate of total loss, but the plaintiffs here cannot get to statistical sampling because they haven't proved that even one claim is actually false, much less that there is a representative rate of falsity from which the number of false claims could be extrapolated.

antibribery regulations, the Court of Appeals held, "violating a regulation is not synonymous with filing a false claim." *Id*. As discussed above, *see* 28-29, *supra*, there must also be proof that a false statement was presented to the government in connection with a claim that seeks to profit from the alleged scheme. *See also, e.g., U.S. ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 741–42 (7th Cir. 2007) *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009) (rejecting FCA claim where plaintiff failed "to present any evidence *at an individualized transaction level* to demonstrate that [defendant] failed to provide an appropriate refund or replacement product for a returned prescription.).

The same result must follow here. Though the plaintiffs have adduced ample evidence to support their allegations that Par colluded with the pharmacies to switch prescriptions to Par's drugs for the purpose of capitalizing on higher reimbursement rates, they have failed to respond to Par's summary judgment motion with proof sufficient to identify any specific claim that a jury could reasonably conclude was false. Simply put, a False Claims Act claim requires evidence sufficient to show that a false claim was made. The plaintiffs, for whatever reason, failed to adduce such evidence on summary judgment.

**e. Conspiracy to Violate the FCA**

The federal government separately alleges a conspiracy to violate the FCA under 31 U.S.C. § 3729(a)(1)(C), which renders it unlawful to "conspire[] to commit a violation" of the substantive provisions of the FCA. *See* CSCA Count IV, ECF No. 231. This claim is based primarily on two factual allegations: (i) "Par conspired with Walgreens and other pharmacy providers to submit false and fraudulent claims for higher priced drugs to evade the federal and state price limits," *see id*. ¶¶ 20-21; and (ii) Par marketed its drugs based on the MACs and FULs that applied to competitors, inducing Walgreens to switch prescriptions, but that when Walgreens

learned it was under investigation, it requested and Par agreed, that Par would provide Walgreens with price reductions on future transactions so that Walgreens could recoup the lost profits from the switching scheme, *see id*. ¶¶ 37-49.

The claim of conspiracy to violate the False Claims Act is governed by general conspiracy principles. *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 n.3 (7th Cir. 1999). A civil conspiracy is simply a combination of persons or entities "acting in concert to commit an unlawful act, or to commit a lawful act by unlawful means." *See Beaman v. Freesmeyer*, 776 F.3d 500, 510 (7th Cir. 2015). Thus, as with any conspiracy, the core burden is to prove an agreement or meeting of the minds. *Durcholz*, 189 F.3d at 545–46. There must be a common purpose for there to be an FCA conspiracy, as the Supreme Court explained with respect to the pre-2010 version of the FCA:

> Under § 3729(a)(3), it is not enough for a plaintiff to show that the alleged conspirators agreed upon a fraud scheme that had the effect of causing a private entity to make payments using money obtained from the Government. Instead, it must be shown that the conspirators intended "to defraud the Government." Where the conduct that the conspirators are alleged to have agreed upon involved the making of a false record or statement, it must be shown that the conspirators had the purpose of "getting" the false record or statement to bring about the Government's payment of a false or fraudulent claim. It is not necessary to show that the conspirators intended the false record or statement to be presented directly to the Government, but it must be established that they agreed that the false record or statement would have a material effect on the Government's decision to pay the false or fraudulent claim.

*Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672–73 (2008) (emphasis added).[15] In assessing whether defendants involved in allegedly conspiratorial conduct shared a

[15] Again, the statute was substantively amended effective 2010; the conspiracy provision no longer refers to a conspiratorial purpose of "getting a false or fraudulent claim paid or approved," and so *Allison Engine* was superseded by statute. *See United States ex rel. Garbe v. Kmart Corporation*, 824 F.3d 632, 640 (7th Cir. 2016). However, the discussion remains relevant. The intent that is now required is "to commit a violation" of the FCA. The Supreme

common goal, the conspiracy's purpose should not be defined in "too narrow or specific terms." *United States ex rel. Miller v. Bill Harbert Int'l Const., Inc.*, 608 F.3d 871, 900 (D.C. Cir. 2010).

Here, the relevant question is whether the plaintiffs have sufficient evidence of a conspiracy between Par and the pharmacies to "commit a violation of" the FCA. 31 U.S.C. § 3729(a)(1)(C). "[T]he *sine qua non* of a conspiracy is not merely knowledge but an agreement." *United States v. Lechuga*, 994 F.2d 346, 358 (7th Cir. 1993). As one court has explained, the "paradigmatic" false claim is "an incorrect description of the goods or services provided or a request for reimbursement for goods or services never provided." *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1031 (D.C. Cir. 2017) (citations omitted); *see Presser* 836 F.3d at 779 (distinguishing between false claims that described the correct treatment but, incorrectly described because of the provider code, and claims that are false by expressly billing for a treatment never given.).

Par argues, first, that there were no false claims at all, and it has been determined already that the claims at issue were not false under the implied false-certification theory of the FCA, but that in itself is not enough to defeat a conspiracy claim. As long as there was a common goal, a conspiracy can be proved without respect to whether the goal was ever accomplished. "The essence of conspiracy, after all, is the agreement to commit an unlawful act; it is therefore not necessary to show that the conspiracy succeeded in its illicit aim." *United States v. Vallone*, 752 F.3d 690, 697–98 (7th Cir. 2014). So, a conspiracy to violate the FCA by obtaining payment on false claims could be proved whether or not the submitted claims were actually false within the meaning of the FCA or were paid by the government.

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Court's statement that "it must be shown that the conspirators intended 'to defraud the Government'" is equally true where the statute says there must be intent to commit an FCA violation—for violating the FCA is just another way of saying "defrauding the government" by submitting a false claim.

Par also contends that the plaintiffs lack any evidence of an agreement between Par and the pharmacies. The government responds that Par and the pharmacies agreed to defraud Medicaid, by way of submitting false claims, for the purpose of increasing their revenues. It cites evidence that, before the switching scheme was implemented, Par had expressly marketed its drugs by pointing out the unfavorable MACs and FULs applicable to its competitors' comparable drugs and had presented financial analyses to the pharmacies that "tout[ed] the tremendous profit opportunities." Pls. Br. 50, ECF No. 369. Par, the government further alleges, also offered misleading information to the pharmacies about relevant laws on substitution and failed to discuss the regulations on medical necessity and economical treatment.[16] It also provided financial incentives, such as rebates and discounts, to perpetuate the pharmacies' participation.

The Seventh Circuit, in another context, has already looked at allegations of a conspiracy between Walgreens and Par. Piggybacking on Lisitza's *qui tam* lawsuits against Walgreens and Par, a non-governmental Third Party Payer—a union health benefits fund—alleged that Walgreens and Par engaged in a RICO conspiracy under 18 U.S.C § 1962(d) (in addition to asserting a claim under § 1962(c)). *See United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co*. et al., 719 F.3d 849 (7th Cir. 2013). The Seventh Circuit affirmed the dismissal of claims under Rule 12(b)(6), taking as true all the allegations in the complaint—which, down to the description of Par's alleged marketing practices and Walgreens' alleged automatic switching system—very closely mirror the allegations in this case (as they naturally would). The Seventh Circuit concluded that the

[16] If Par provided false information to the pharmacies about the legality of the scheme, as the plaintiffs argue, see Pls. Mem. 15, ECF No. 369, it is difficult to see how that is evidence of a knowing agreement by the pharmacies.

complaint failed to plausibly allege the existence of the "enterprise" required by RICO because of insufficient allegations pertaining to coordination between Walgreens and Par. *See id*. at 856.

This case, of course, is far beyond the pleading stage and is subject to a different standard. The framework of the Seventh Circuit's analysis, however, still suggests what a plaintiff would be required to plead and, ultimately, prove to succeed on a conspiracy claim in this context. Notably, the Court examined whether it would be reasonable to infer that Walgreens could not have accomplished the scheme on its own "by simply purchasing expensive dosage forms from Par and other manufacturers…and filling prescriptions with these expensive dosage forms on its own initiative." 719 F.3d at 856. Some cooperation "outside the bounds of the parties' normal commercial relationship" would be suggestive of improper collusion. *Id*. But without an indication "how the cooperation in this case exceeded that inherent in every commercial relationship between a drug manufacturer and a pharmacy," both the substantive RICO claim and the conspiracy claim failed. *Id*.

But unlike in *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund*, the plaintiffs here have established more than existence of a mutually beneficial commercial relationship; it is a relationship forged over an agreement to bring about a common purpose, namely to increase their profits by engaging in dosage-form substitution. A conspiratorial agreement need not be express. "To be liable as a conspirator you must be a voluntary participant in a common venture, although you need not have agreed on the details of the conspiratorial scheme or even know who the other conspirators are. It is enough if you understand the general objectives of the scheme, accept them, and agree, *either explicitly or implicitly*, to do your part to further them." *Jones v. City of Chicago*, 856 F.2d 985, 992 (7th Cir. 1988) (emphasis added).

Here, there is evidence that Par specially developed or acquired the rights to atypical drugs and knowingly marketed them to pharmacies on the basis that, at least temporarily, they would yield higher reimbursement rates. It then specifically and aggressively marketed these drugs (which were not typically prescribed or dispensed) by encouraging pharmacies to routinely switch to the subject drugs, solely for their own profit motive and without regard to whether the switching was either medically necessary or economical. Par incentivized or rewarded the pharmacies with financial benefits for swapping in Par's drugs. Further, marketing materials (including Par's financial projections) and the testimony of witnesses from Par and pharmacies show that there was nothing clandestine about the arrangement. It is true that the pharmacies *could have* effected a switching plan on their own, just by purchasing Par's atypical drugs and engaging in dosage form substitution. But in this case the evidence shows that the pharmacies did not act spontaneously, and that the prescription-switching scheme was, in essence, a joint venture. The "agreement" element is certainly not lacking evidentiary support in the summary-judgment record.

But the question remains whether what the parties agreed to completes the second requirement of the conspiracy statute—agreement to violate the FCA—here, by causing the presentation of a ***"false or fraudulent claim for payment***." See 31 U.S.C. § 3729(a)(1)(A). It is often said (including earlier in this opinion) that the FCA is not a general anti-fraud statute; neither is it a general anti-conspiracy statute. The object of the conspiracy must be to make false or fraudulent claims.[17] Moreover, it is not self-evident, as the government seems to think, that a

[17] As discussed further with respect to the common-law fraud claim, the United States cannot—or certainly has not explained why it can—avail itself of the protection of state common-law torts such as general "civil conspiracy." Therefore this discussion as to the United States is limited to the FCA anti-conspiracy provision. The state plaintiffs do not raise any

conspiracy to violate Medicaid law (as opposed to a conspiracy to make false claims) is covered by § 3729(a)(1)(C). And, in this case, this is the only common purpose supported by the plaintiffs' evidence: an agreement to exploit loopholes in Medicaid's MAC system for profit, which (even assuming *arguendo*) violates Medicaid but is distinct from the intent to defraud the government with false claims. The FCA punishes the knowing submission of false claims; abject corporate profit-seeking is not in its purview.

So if the conspiracy here is not to violate the FCA, but to engage in a course of conduct that violates some other substantive law such as the Medicaid laws and regulations, it falls outside the FCA's conspiracy provision. The Court finds no authority for the proposition that the FCA conspiracy provision applies not only to a conspiracy to violate the substantive provisions of the FCA but also to a conspiracy to violate some other statutory scheme. The plaintiffs point to none. And the express language of the statute is to the contrary; there must be a "conspiracy to commit a violation of subparagraph (A, (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C). It is also inconsistent with how courts construe other statutes that contain anti-conspiracy provisions. For example, a conspiracy to violate the RICO statute requires an agreement to participate in an endeavor that, "if completed, *would constitute a violation of the substantive statute.*" *DeGuelle v. Camilli*, 664 F.3d 192, 204 (7th Cir. 2011) (quoting *Goren v. New Vision Int'l, Inc*., 156 F.3d 721, 732 (7th Cir.1998)) (emphasis added). In this case, where the record contains insufficient evidence that false claims were presented, the course of conduct that the parties agreed to would not constitute a substantive violation of the FCA, but instead a violation of the laws and rules of Medicaid. (The plaintiffs' proof is consistent with an agreement to

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arguments specific to their states' common law of conspiracy, and therefore have forfeited any argument for failure to develop it.

participate in conduct that arguably[18] violates Medicaid rules.) However, as discussed at length above, the Seventh Circuit holds that violating a regulatory scheme is not one and the same with submitting a false claim for the purposes of the FCA.

If there is some cognizable claim of conspiracy to violate Medicaid law, it is not found under § 3729(a)(1)(C) of the False Claims Act, at least not as far as the plaintiffs have established.[19] And the Court cannot read the plaintiffs' pleadings and briefs to raise any other theory of liability for conspiracy. *See* n. 7, *supra*. Therefore, Par has established that it is entitled to judgment as a matter of law with respect to the claim that the scheme was an FCA conspiracy.

**B. Common Law Fraud**

All of the plaintiffs allege fraud by Par. The United States, however, does not explain the legal basis for its claim. This Court, of course has original jurisdiction over all civil actions brought by the United States under 28 U.S.C. § 1345, but the jurisdictional statute does not relieve the United States of bringing a cognizable claim.[20] With respect to its putative "common

[18] The Court need not resolve the parties' arguments about what the provisions requiring treatment to be medically necessary and economical mean or what conduct they prohibit. In resolving the conspiracy claim, the Court assumes without deciding that the prescription switches violated one or both of those standards.

[19] Indiana, for example, has asserted a claim of Medicaid fraud, and aiding and abetting such fraud, under its state statutes.

[20] *See Volodarskiy v. Delta Airlines, Inc.*, 784 F.3d 349, 350 (7th Cir. 2015) (notwithstanding federal jurisdiction, private right of action under EU law not cognizable or "judicially enforceable"). *Cf. Nat'l Farmers Union Ins. Companies v. Crow Tribe of Indians*, 471 U.S. 845, 850–51 (1985):

> Section 1331 of the Judicial Code provides that a federal district court "shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States. It is well settled that this statutory grant of jurisdiction will support claims founded upon federal common law as well as those of a statutory origin. Federal common law as articulated in rules that are fashioned by court decisions are 'laws' as that term is used in § 1331. Thus, in order to invoke a federal district court's

law" fraud claim, the United States does not point to any governing law, and there is no general fraud cause of action in federal law. (With its conspiracy claim, the United States' foothold was a federal statute.) There are myriad federal anti-fraud statutes, such as the securities and tax laws, the mail and wire fraud statutes, and of course, the False Claims Act. But from whence comes the separate fraud common-law tort that the United States asserts here in Count IV of its operative complaint? Its briefs are silent. Fraud is a state-law tort, and the United States' jurisdictional statement invokes 28 U.S.C. § 1367 (supplemental jurisdiction), so presumably the United States bases its "common law fraud" claim on state law, but it does not invoke the common law of any one state as the legal predicate of Count IV. The case law it cites, see Pls. Br. 51, ECF No. 369, hails from Illinois and Michigan, but it has not explained why it enjoys the protections of the tort laws of these, or every, state.

But though there is reason to question on what basis the United States may assert an Illinois (or Michigan, or Indiana) tort cause of action, Par, hoping to cut out all the fraud claims in one fell swoop based on the absence of any "false" claim, does not differentiate between them or examine the legal underpinnings of the United States' common-law claim. It has, in other words, forfeited any objection to considering the merits of the United States' common law fraud claim, so the Court will consider that claim along with the similar claims of Michigan and Indiana.

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> jurisdiction under § 1331, it was not essential that the petitioners base their claim on a federal statute or a provision of the Constitution. It was, however, necessary to assert a claim arising under federal law.

All of the common law fraud claims can be examined, and dispatched, as a group, because they fail for the same reason the FCA claims fail, namely the absence of false statement or misleading representation. Under Indiana law, "[t]o prove fraud, a plaintiff must establish the following elements: (1) a material misrepresentation of past or existing fact which (2) was untrue, (3) was made with knowledge of or in reckless ignorance of its falsity, (4) was made with the intent to deceive, (5) was rightfully relied upon by the complaining party, and (6) which proximately caused the injury or damage of which the plaintiff complains. *Angel v. Powelson*, 977 N.E.2d 434, 445 (Ind. Ct. App. 2012) (citing *Lawyers Title Ins. Corp. v. Pokraka*, 595 N.E.2d 244, 249 (Ind. 1992)). Similarly in Michigan, the elements of the tort of fraud are "(1) [t]hat defendant made a material representation; (2) that it was false; (3) that when he made it he knew it was false, or made it recklessly, without any knowledge of its truth and as a positive assertion; (4) that he made it with the intention that it should be acted upon by plaintiff; (5) that plaintiff acted in reliance upon it; and (6) that he thereby suffered injury." *Lawrence M. Clarke, Inc. v. Richco Const., Inc.*, 489 Mich. 265, 283–84, 803 N.W.2d 151, 162 (2011) (citing *Scott v. Harper Recreation, Inc.*, 444 Mich. 441, 446 n. 3, 506 N.W.2d 857 (1993)).

The plaintiffs do not delineate the defendant's purported false and material misrepresentations in the single paragraph of their response brief that addresses the common-law fraud claim. This Court therefore infers that that they base the claims upon the same representations underlying their FCA claim (otherwise, they would have forfeited their fraud argument for failure to develop it). The element of "falsity," therefore, is again at the fore. And the Court has already determined that the claims at issue did not contain representations that were false or misleading either on their face or by omission. A common-law cause of action for fraud that is based on the exact same representations cannot withstand that conclusion.

### C. Theft, Offense against Property, and Unjust Enrichment Claims

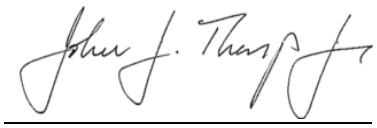
The States assert other violations of their common law arising from Par's role in the pharmacies' prescription-switching. Michigan and Indiana both assert that Par committed unjust enrichment, and Indiana adds a theft claim. This Court discretionarily declines to exercise the supplemental jurisdiction over those claims *See* 28 U.S.C. § 1367(c); *United States ex rel. Bogina v. Medline Indus., Inc*., 809 F.3d 365, 367 (7th Cir. 2016). They are dismissed without prejudice.

Michigan and Indiana, of course, allege that their own FCA-equivalent statutes were violated. It is difficult to imagine how those claims could survive where the parties have agreed that liability under the federal and state FCAs is coextensive. But, the courts of those states are better positioned to address the nuances of their own statutes, to the extent preclusion doctrines would permit them to be re-asserted in state court. Therefore, this Court declines to exercise supplemental jurisdiction over the claimed violations of state false-claims statutes, too.

* * * * *

There is no doubt that the evidence in this case suggests a collaboration between Par and the pharmacies to drive up their own profits by exploiting loopholes in the Medicaid reimbursement system. Whether that endeavor is worthy of public approbation or opprobrium is not the question presented here. It bears repeating, in the words of the Ninth Circuit, *see* p. 37, *supra*, that the FCA "focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme." The question presented by Par's motions for summary judgment is whether the reimbursement claims for the subject drugs were false because they omitted information about the collaboration between Par and the pharmacies and whether it violated Medicaid regulations. The plaintiffs failed to adduce

sufficient evidence to support a jury verdict that the reimbursement claims were false or misleading for that reason, and on that basis, Par's motions for summary judgment are granted.



Date: May 10, 2017

John J. Tharp, Jr.
United States District Judge